Webinar: Informed Consent for Vulnerable Populations

Note: *This webinar took place on the 03/21/2016. You can find a video recording and the presentations used during the webinar below.*

Webinar introduction

In the current Clinical Trials Directive, the definition of conditions for inclusion of vulnerable populations is limited to clinical trials with minors and incapacitated adults who are not able to give informed legal consent. Released in April 2014, the new "EU Clinical Trial Regulation" (EU Regulation 536/2014) expands on information given for the above populations. Additionally, it also goes further and defines the conditions, especially the informed consent process for clinical trials in pregnant and breast feeding women as well as in emergency situations. Although, the objective is to harmonise the performance of clinical trials in Europe, certain opt-out options for Member States are foreseen and thus might lead to exclusion of certain countries from some trials.

Webinar agenda

Time	Agenda
17.00	Welcome and introductions **Lode de Wulf**, *UCB Biopharma*

Time	Agenda
17.10	“Protection of subjects and informed consent – the clinical trials regulation and the inclusion of minors and pregnant and breastfeeding women in research on medicinal products” **Andrea Heckenberg,** *Medical University of Vienna & EUPATI Consortium Member*
17.25	Q & A – Panel members: **Joan Jordan**, *MS Ireland & EUPATI Trainee* and **Adriana Ceci**, *Scientific Director of the CVBF (Consorzio per Valutazioni Biologiche e Farmacologiche) & President of the Gianni Benzi Pharmacological Research Foundation*
17.50	“Protection of subjects and informed consent – the clinical trials regulation and the inclusion of patients incapacitated to give consent and in emergency situations in research on medicinal products” **François Lemaire**, *Professor Emeritus of medical intensive care at Université Paris Est Créteil*
18.05	Q & A – Panel members: **Joan Jordan**, *MS Ireland & EUPATI Trainee* and **Adriana Ceci**, *Scientific Director of the CVBF (Consorzio per Valutazioni Biologiche e Farmacologiche) & President of the Gianni Benzi Pharmacological Research Foundation*
18.30	Close of the Webinar

Webinar recording

Webinar presentations

Presentation 1: Protection of subjects and informed consent – the clinical trials regulation and the inclusion of minors and pregnant and breastfeeding women in research on medicinal products

Speaker: **Andrea Heckenberg,** *Medical University of Vienna & EUPATI Consortium Member*

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Presentation 2: Informed consent for incapacitated patients and in emergency situations

Speaker: **François Lemaire**, *Professor Emeritus of medical intensive care at Université Paris Est Créteil*

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